

K960906

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Summary of Safety and Effectiveness

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Common Name: Glenoid Component for the Foundation™ Total Shoulder System

Classification Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis per CFR 888.3660

Description: The glenoid is fabricated from UHMWPE (ASTM F648). The articulating surface has a radius of curvature greater than the corresponding humeral head. This mismatch between the glenoid and humeral head allows for translation of the head in the superior/inferior and anterior/posterior directions. The back surface of the component is spherical in geometry and has either a keel or three pegs for fixation in the glenoid. These glenoid components are 4 mm thick and available in five sizes for each component, the keeled and pegged components.

Intended Use: This total shoulder prosthesis is intended for treatment of patients who are candidates for total shoulder arthroplasty because the natural humeral head and/or glenoid has been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis or proximal humeral fracture, and revision arthroplasty where bone loss is minimal. This system includes a humeral stem and head and is to be used with bone cement. These devices are intended to aid the surgeon in relieving the patient of shoulder pain and restoring shoulder motion.

Comparable Features to Predicate Device(s):

Encore Foundation™ Total Shoulder System
Kirshner Neer II™ Glenoid Component
Intermedics Select™ Shoulder Glenoid Component